

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>TAKEDA PHARMACEUTICALS USA, INC.,</b>	:	
<b>Plaintiff</b>	:	<b>Case No. 2:17-cv-00452-JHS</b>
<b>v.</b>	:	
<b>SPIRIDON SPIREAS,</b>	:	
<b>Defendant</b>	:	

**ORDER**

AND NOW, this \_\_ day of \_\_\_\_\_, 2017, upon consideration of Defendant Spiridon Spireas's Motion to Dismiss and Plaintiff Takeda Pharmaceutical USA, Inc.'s Response thereto, it is hereby ORDERED that Defendant's Motion is GRANTED and Plaintiff's Complaint is hereby DISMISSED.

BY THE COURT:

\_\_\_\_\_  
JOEL H. SLOMSKY, J.

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FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>TAKEDA PHARMACEUTICALS USA, INC.,</b>	:	
<b>Plaintiff</b>	:	<b>Case No. 2:17-cv-00452-JHS</b>
v.	:	
<b>SPIRIDON SPIREAS,</b>	:	
<b>Defendant</b>	:	

**DEFENDANT'S MOTION TO DISMISS**

Pursuant to Federal Rule of Civil Procedure 12, Defendant Spiridon Spireas, Ph.D. hereby moves to dismiss the Complaint filed by Plaintiff Takeda Pharmaceuticals USA, Inc.

The reasons for this Motion are more fully set forth in the accompanying Memorandum of Law, which is incorporated herein by reference.

WHEREFORE, Defendant Spiridon Spireas, Ph.D. respectfully requests that this Court enter an Order dismissing the Complaint and all claims against him by Plaintiff Takeda Pharmaceuticals USA, Inc.

Respectfully submitted,

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Date: April 3, 2017

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**DEFENDANT’S MEMORANDUM OF LAW  
IN SUPPORT OF HIS MOTION TO DISMISS**

Date: April 3, 2017

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Defendant Spiridon Spireas, Ph.D. (“Dr. Spireas” or “Defendant”) submits this Memorandum of Law in support of his Motion to Dismiss.

## **I. INTRODUCTION**

Plaintiff Takeda Pharmaceuticals USA, Inc. (“Takeda”) claims to be the successor in interest of Mutual Pharmaceutical Corporation (“Mutual”). (Complaint, ¶1.) Takeda claims that prior to its succession, Mutual had been duped for ten years into paying \$150 million in royalties to Hygrosol Pharmaceutical Corp. (“Hygrosol”) for the sales of two drug products (propafenone and felodipine) that Takeda now suggests – but fails to actually plead – were not formulated using patented technology subject to a License Agreement between Hygrosol, Dr. Spireas, and Sanford M. Bolton, Ph.D., on the one hand, and Mutual and United Research Laboratories, Inc. (“URL”), on the other (the “1998 Hygrosol License Agreement”). Takeda attaches the 1998 Hygrosol License Agreement to its Complaint as Exhibit A. Tellingly, Takeda did not sue Hygrosol, or the other parties to the Agreement, and has only sued Dr. Spireas.<sup>1</sup> It also conspicuously omitted URL from this lawsuit, despite the fact that URL, Mutual and Takeda are all represented by the same lawyers, that URL made each and every royalty payment to Hygrosol under the 1998 Hygrosol License Agreement, and that Mutual/Takeda made none.

Mutual and URL already sued Dr. Spireas, Hygrosol and the Estate of Bolton in state court claiming that they were tricked into paying the same royalties paid under the same 1998 Hygrosol License Agreement at issue in this case, and seeking the same relief sought in this case, *i.e.*, a return of the same exact royalties. *See* Exhibit “A” for Mutual’s state court Complaint.

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<sup>1</sup> This latest federal lawsuit is a personal attack on Dr. Spireas in an attempt to exert economic leverage on him and to extort a settlement of his and his companies’ claims against Mutual in the prior pending state court actions described below.

Mutual lost, and is now forum shopping. *See* Exhibits “B” and “C.”<sup>2</sup> After having lost, Takeda launched this duplicative and duplicitous diversity suit based on the same core averment that Dr. Spireas allegedly tricked Mutual into paying royalties to Hygrosol pursuant to the 1998 Hygrosol License Agreement. (Complaint, ¶¶6-31.) *Res judicata* bars this second lawsuit.<sup>3</sup>

Additionally, Takeda’s re-tooled federal Complaint is so implausible that it is absurd. Takeda’s keystone allegation for all of its various claims is that Dr. Spireas lied to Mutual when he “consistently *represented* to Mutual that the generic felodipine and propafenone formulations in the felodipine and propafenone ANDA submissions used the patented liquisolid technology,” thus entitling him to royalties. (Complaint, ¶48 (emphasis added).)

Takeda’s entire lawsuit, therefore, is based upon the preposterous allegation that Mutual did not know how it manufactured its own products in its own manufacturing facility for ten or more years. This is patently not plausible, especially in the highly regulated drug industry.<sup>4</sup>

Significantly, Takeda’s claims are also clearly barred by the statute of limitations, except

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<sup>2</sup> The Court may take judicial notice of the prior state court lawsuits. *Oneida Motor Freight, Inc. v. United Jersey Bank*, 848 F.2d 414, 416 n.3 (3dCir.1988), *cert. denied*, 488 U.S. 967 (1988). *See also Conceicao v. Nat’l Main Cleaning Co.*, 650 Fed. Appx. 134, 135 (3dCir.,2016)(court may take judicial notice of the records of a prior proceeding, particularly where *res judicata* is raised). The Court may also do so because the Complaint specifically pleads their existence at ¶¶ 78, 81, 83 and 84, and may consider other publicly available records, including the parties’ ANDAs and patents. *Pensions Benefit Guaranty Corp. v. White Consol. Indus. Inc.*, 998 F.2d 1192, 1196 (3dCir.,1993).

<sup>3</sup> Pursuant to Pennsylvania Superior Court Operating Procedure §65.37, which prohibits citation to unpublished opinions, Defendant Spireas is citing to and attaching as Exhibit “C” the April 3, 2017 Superior Court Unpublished Opinion in *Mutual v Spireas* (Pa. Super. No. 1287 EDA 2016), only for purposes of *res judicata*.

<sup>4</sup> *See* 21 C.F.R. § 210.1(a) (Food & Drug Administration (“FDA”) regulates the manufacturing, processing, packing, and holding of a drug through its Current Good Manufacturing Practice (“CGMP”) regulations). During the entire time Mutual made felodipine and propafenone, its employees were required to follow precise formulas and instructions for each and every step. *See* 21 C.F.R. § 210.1(b) (failure to comply with the CGMP regulations renders the drug at issue “adulterated,” and such drug, and the persons responsible for the failure to comply with the CGMP regulations, shall be subject to regulatory action).

for Count II for breach of contract, which must be dismissed for the other reasons set forth in this Memorandum. The only allegations against Dr. Spireas relate to three formal reports from 2000. (Complaint, ¶¶48-58.) Mutual fired Dr. Spireas in 2004. (Complaint, ¶54.) Mutual sued Dr. Spireas for the same claims in 2011, which were dismissed. *See* Exhibit “B.” Seventeen (17) years after any alleged misrepresentation, thirteen (13) years after Mutual fired Dr. Spireas, and six (6) years after it sued him, Takeda filed this redundant and frivolous lawsuit. No fraudulent tolling doctrine can resurrect a 17 year old claim after years of multiple litigations.

Takeda’s artfully pleaded allegation that Dr. Spireas misled Mutual is itself based on a mischaracterization in ¶¶67-71 and 79-84 of an out-of-context and incomplete answer to a question in a tax trial – a mere snippet of testimony.<sup>5</sup>

Tellingly, Takeda does not allege that Mutual’s generic drugs were not actually developed using the patented technology, but only that Dr. Spireas supposedly stated they were not fourteen (14) years later in a tax dispute. (Complaint, ¶64.) Takeda seizes on this purported statement to convey the sense that a tort or breach occurred, but it then also pleads the essential fact in Paragraph 75 of the Complaint that makes the alleged tort or breach impossible, which is that it did in fact use the technology.

No matter what Dr. Spireas allegedly said in a tax trial three (3) years ago in 2014, which was fourteen (14) years after the alleged misrepresentation, or how Takeda distorts it, Mutual knew precisely how it was making its products during the previous decade, and it knows that its

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<sup>5</sup> In paragraphs 17 and 64 of the Complaint, Takeda cites to this 2014 tax court testimony by Dr. Spireas, which it calls “recent.” The cited testimony is an out-of-context “inaudible” and “scratched” snippet from the tax court that is the sole source of its “evidence.” *See* Exhibit “D” for the actual testimony. Takeda’s Complaint spends sixteen (16) paragraphs of allegations on this **one page of tax court testimony**, in an attempt to make it appear that it is significant. (Complaint, ¶¶17, 60, 61, 64, 67-71, 79-84, 93.) After this, Takeda repeatedly pleads its factual allegations on “information and belief.” (Complaint, ¶¶ 19, 20, 21, 41, 51, 59, 88, 96, 97.) This fails the particularity standards of Fed.R.Civ.P. 9(b) for pleading fraud.

manufacturing process used the patented liquisolid technology, which required payment of royalties. Takeda's failure to plead that it did **not** use the Hygrosol technology is fatal, and requires dismissal of its Complaint.<sup>6</sup>

## **II. STATEMENT OF THE FACTS**

The 1998 Hygrosol License Agreement permitted Mutual and URL to retain Hygrosol to formulate drugs and drug products using technology developed by Hygrosol, including Liquisolid Technology, which is a technique that allows drug manufacturers to, among other things, formulate drug products to include active ingredients that do not dissolve well in water. (Complaint, ¶7, Ex.A.) After the 1998 Hygrosol License Agreement was signed, Dr. Spireas and/or Dr. Bolton obtained four patents relating to various methods of applying Liquisolid Technology in drug formulation and manufacturing which were included in the Technology licensed to Mutual and URL under the 1998 Hygrosol License Agreement. (*E.g.*, Complaint, ¶¶32-34.)

Takeda's repackaging of Mutual's claims is simply impossible: Mutual itself manufactured and sold the two generic drugs subject to the license fee obligations described in the 1998 Hygrosol License Agreement. One of those drugs (felodipine), which accounts for 98% of the royalties at issue, was manufactured and sold by Mutual **after Dr. Spireas left its employment in 2004**. (Complaint, ¶¶ 54, 58, 59.) For the next decade, Mutual manufactured

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<sup>6</sup> Similarly, its conspicuous failure to name its own "sister company," and its own co-litigant in the state court action, URL, is fatal and requires dismissal for failure to join an indispensable party. URL is a fully executed contracting party to the 1998 Hygrosol License Agreement. (Complaint, Ex.A.) URL, not Mutual and not Takeda, made each and every royalty payment which Takeda here seeks to recover. This action necessarily and directly impacts URL's rights. Takeda did not name this contracting party, URL, as a litigant party because doing so would have destroyed diversity and put this case right back before the same state court that dismissed its prior attempt to retake the royalties properly paid to Hygrosol. Takeda's gambit is pure gamesmanship.

and sold those drug products to American consumers day after day, year after year, out of its Philadelphia drug making facility. (Complaint, ¶59.) The products were never manufactured or sold by Hygrosol, Dr. Spireas or Dr. Bolton.

Significantly, in its Complaint, Takeda admits, as it must, that the “nonvolatile solvents” that serve as the linchpin of Dr. Spireas’s technology were actually used in making these drugs, but, according to Takeda, that was only done to deceive Mutual. (Complaint, ¶¶ 75, 96.) This astounding assertion suggests that Mutual has been illegally selling pharmaceutical drugs to the public for more than a decade without actually knowing or understanding the process by which it was making them, and, further, that the process for making the drugs includes unnecessary steps meant only to deceive *the actual maker of the drug*. Yet, somehow, the FDA – with its exacting scrutiny – approved Mutual’s ability to manufacture the drugs based upon those processes to sell them to American consumers. (Complaint, ¶¶ 57, 58.) Moreover, this is a specific and pleaded admission that, in fact, Mutual *did* use the Hygrosol Technology.

To term Takeda’s claim as “implausible” understates its assertion here that Mutual was ignorant of its very own drug making process and recklessly manufactured and sold two pharmaceutical drugs to American consumers without actually knowing how it was making them. (Complaint, ¶¶ 32-34; 57-59.)

For a decade, Mutual followed the formulation developed by Hygrosol and licensed to it, which formula included identifying for Mutual the ingredients to use, how to mix the ingredients, what order to use when mixing the ingredients, how to mill the mixed ingredients, how to dry the mixed ingredients, how long to dry the mixed ingredients, how to granulate the mixed ingredients, and how to put the mixture into a pill making machine and cause it to be extruded from the machine in pill form. *Id.* See 21 C.F.R. § 210.1(a) (FDA CGMP regulations); 21

C.F.R. § 210.1(b) (failure to comply with the CGMP regulations renders the drug adulterated).

Indeed, Mutual spent years in federal court defending AstraZeneca's claim that the Mutual formulation *licensed from Hygrosol* for one of the drugs, felodipine, infringed on the patented process *belonging to AstraZeneca* for the branded drug Plendil. *See, e.g., AstraZeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339-1340 (Fed.Cir.,2004).<sup>7</sup> Mutual ultimately prevailed in that litigation because Dr. Spireas's formulation used PEG 400 as a solubilizer, which the Federal Circuit concluded defeated AstraZeneca's claim of infringement. *Id.* Ironically, PEG 400 is a non-volatile liquid. In other words, the only reason Mutual ended up selling a generic felodipine drug at all without running afoul of AstraZeneca's patent on the branded drug was because Dr. Spireas's formulation actually and necessarily used a non-volatile liquid.

No one can suspend belief or common sense long enough to swallow the Takeda/Mutual pretense that it paid Hygrosol \$150 million because, after making drug products for years and years, it did not actually know the process that it *itself* used. Yet, somehow, Takeda asks this Court to believe that Mutual, and all of its employed scientists, have been ignorant as to how they have been making these two drugs, felodipine and propafenone, for more than a decade. Takeda's claims of such corporate recklessness in the highly-regulated pharmaceutical industry is patently incredible and implausible.

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<sup>7</sup> The formulation developed by Dr. Spireas for Mutual's felodipine product used, *inter alia*, the allowed claims in the fourth patent subject to the 1998 Hygrosol License Agreement. As part of the *AstraZeneca* litigation, that formulation was scrutinized by the Court and by experts for both Mutual and AstraZeneca. *See AstraZeneca AB v. Mutual Pharmaceutical Co., Inc.*, 278 F.Supp.2d 491, 520 (E.D.Pa.,2003), *rev'd*, 384 F.3d 1333, 1339-1340 (Fed.Cir.,2004).

**A. Mutual And URL Entered Into A Contract With Hygrosol In Which Dr. Spireas Has An Ownership Interest To Utilize Its Technology To Manufacture Drug Products.**

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In the late 1990s, Mutual and its sister company, URL, were in a financially precarious position. Mutual executives had previously pled guilty to several felonies relating to the sale of adulterated drugs and making false statements to the FDA. Mutual was anxious to reestablish itself as a viable business. In order to do so, Mutual was trying to locate technology that it might license for purposes of developing drug products that would have commercial success and might improve the company's current state of near bankruptcy.

**1. The 1998 Hygrosol License Agreement**

In 1997, Dr. Spireas and Sanford M. Bolton, Ph.D. received notice that the Patent and Trademark Office ("PTO") had allowed them a patent relating to a novel technique that could be applied to formulate certain kinds of water insoluble drug products. (Complaint, Ex.A.) Dr. Spireas and Dr. Bolton formed Hygrosol to serve as the assignee of the patent and related technology ("Hygrosol Technology") and as the vehicle for them to make commercial use of their invention. *Id.*

In 1998, Mutual, URL, Hygrosol, Dr. Bolton and Dr. Spireas entered into the 1998 Hygrosol License Agreement whereby Mutual could receive an exclusive license for drug products using Hygrosol Technology. *Id.* In return, Mutual agreed to pay royalties to Hygrosol. *Id.* at § 4.2.<sup>8</sup> As indicated in the "Engagement Letter," attached as Exhibit B to Takeda's

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<sup>8</sup> Takeda refers to the Technology described in the License Agreement, but changes the name of the "License Agreement" to the "Liquisolid Agreement." (Complaint, at p.1.) However, Mutual paid Hygrosol the same royalties at issue here in this re-tooled federal action that were in dispute in the state court *Mutual v Spireas* action. See Exhibits "A," "B" and "C." Takeda did not sue Hygrosol in this federal action, and even refers to the 1998 Hygrosol License Agreement as the "Liquisolid Agreement" to try to suggest that there is a difference in the claim and a difference in the real parties in interest. There is not. Indeed, Paragraph 19 of the 1998 Hygrosol License



Complaint, Dr. Spireas's work under the 1998 Hygrosol License Agreement specifically included working on the development of the two drugs at issue in this lawsuit, namely, felodipine and propafenone. (Complaint, ¶1 and Ex.B.)

## 2. Dr. Spireas Developed Various Pharmaceutical Drugs Using The Liquisolid Technology While Employed At Mutual

As Takeda admits, Dr. Spireas worked with Mutual's scientists to develop the two drugs (Complaint, ¶ 12), and both of those drugs were developed using "nonvolatile solvents," which Takeda admits are the foundation of Dr. Spireas's work and the Hygrosol Technology. (Complaint, ¶¶ 32, 33, 75, 96.) Therefore, this factual allegation directly contradicts the missing keystone allegation that Mutual did *not* use the Hygrosol Technology.<sup>9</sup>

Without the allegation that Mutual did *not* actually use the Hygrosol Technology, there cannot be any misrepresentation. In other words, regardless of whether Dr. Spireas's snippet of testimony 14 years later could be construed to mean that Mutual did not use the Hygrosol Technology, the fact that Mutual pleads that it *did* use it means that it could not have been

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Agreement plainly states that Hygrosol – not Dr. Spireas – is the real party in interest to be paid royalties. (Complaint, Ex.A, ¶19.) Takeda/Mutual, the identical payor-party in interest, is improperly pursuing the identical damages in this federal action that were dismissed in the state court action.

<sup>9</sup> Takeda baselessly alleges, upon "information and belief," that at the time of the Engagement Letter in March 7, 2000, "Spireas was already aware that the patented liquisolid technology would not work for formulating felodipine or propafenone." Without this allegation, there is no *scienter* element and no fraud or fiduciary claim. Not surprisingly, Takeda offers absolutely no indication of what "information" it has to support this allegation or what good faith basis it has to "believe" it. Instead, Takeda improperly postures that its unfounded accusations are based upon purported "information and belief" that do not exist. As set forth above, very tellingly, nowhere in its Complaint does Takeda actually allege that Dr. Spireas's technology was *not* used in making these two drugs. Instead, Mutual only alleges that Dr. Spireas purportedly said in the IRS trial fourteen (14) years later that it was not used after he had told Mutual it *was* being used *by Mutual*. Certainly, if it were true that the technology was not used, then Mutual, which holds all of the confidential and proprietary information, and actually made the drugs in its own facility, would know this and would have made it the focal point of this lawsuit by pleading it clearly and unequivocally.

defrauded.

In June and September of 2000, Mutual submitted Abbreviated New Drug Applications (“ANDAs”) to the FDA for generic felodipine extended-release tablets and propafenone tablets. (Complaint, ¶¶ 46, 47.) According to Takeda, in November 2001, the FDA approved Mutual’s ANDA for generic propafenone and, shortly thereafter, Mutual itself began selling the drug. (Complaint, ¶57.)

Also according to Takeda, in February 2004, the FDA approved Mutual’s ANDA for generic felodipine extended-release tablets and it began selling that drug in “late 2004.” (Complaint, ¶58.) Takeda conveniently fails to disclose why it took approximately four (4) years to obtain approval for felodipine when it took less than two years for approval of propafenone. There is a good reason for this. In late 2004, after Dr. Spireas was no longer employed at Mutual, Mutual prevailed in its litigation with AstraZeneca. *See AstraZeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339-1340 (Fed.Cir.,2004). As a result, Mutual was able to begin manufacturing and selling its generic felodipine.<sup>10</sup>

Pursuant to the terms of the 1998 Hygrosol License Agreement, Mutual paid Hygrosol \$3.7 million in propafenone royalties and \$146.4 million in felodipine royalties between 2002 and 2012. (Complaint, ¶59.) Pursuant to the terms of the 1998 Hygrosol License Agreement, these royalties constituted twenty percent (20%) of the gross profits from the sale of these drugs. (Complaint, Ex.A, §4.1.) In other words, Mutual realized over \$600 million dollars in profits during this same time frame for the sale of the drugs developed by Dr. Spireas and using the

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<sup>10</sup> In September 2004, notwithstanding his considerable contributions to Mutual, including his aid in defense of the felodipine generic patent, Mutual terminated Dr. Spireas without cause. (Complaint, ¶54.) Dr. Spireas’s termination followed a long period of tension between Dr. Spireas and Richard Roberts, M.D., Ph.D., Mutual’s CEO, over issues such as management and communication styles.

Hygrosol Technology.

**B. The Prior Pending State Court Actions**

**1. Mutual Previously Sued Dr. Spireas In State Court For The Same Damages And Claims Relating To The 1998 Hygrosol License Agreement And Lost.**

In early 2011, apparently unhappy that it had to share a portion of the hundreds of millions of dollars from the sale of the drugs Dr. Spireas undeniably developed, Mutual sued him claiming that he was not entitled to the royalties it had paid to Hygrosol for over a decade under the 1998 Hygrosol License Agreement. *See* Exhibit “A.” That case is pending at *Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. v. Spiridon Spireas, Estate of Sanford M. Bolton, and Hygrosol Pharmaceutical Corp.*, C.C.Phila., Civil Action No. 11-05-00741 (“*Mutual v. Spireas*”). Any arguable tolling of any arguable statute of limitations stopped right there and then when Mutual filed its lawsuit.<sup>11</sup> The state court dismissed Mutual’s and URL’s claims on summary judgment. *See* Exhibit “B.” On April 3, 2017, the Pennsylvania Superior Court affirmed the dismissal. *See* Exhibit “C.”

Like here, Mutual and URL, the two signatories to the 1998 Hygrosol License Agreement, contended that they had been tricked into paying the same approximately \$150 million licensing fees to Hygrosol, Dr. Spireas and Dr. Bolton pursuant to the terms of the same 1998 Hygrosol License Agreement. *See* Exhibit “A,” *Mutual v. Spireas* Complaint at ¶¶ 38-39.

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<sup>11</sup> That lawsuit, though meritless, was properly brought by both Mutual and URL as the two related companies who entered into the contract with Dr. Spireas, Dr. Bolton and Hygrosol. (Complaint, Ex.A.) Takeda recognizes that Mutual and URL are the two signatories to the 1998 Hygrosol License Agreement, but, troublingly, filed this federal lawsuit claiming only to be the successor to Mutual – not URL. (Complaint, ¶¶ 1, 18.) Takeda appears either not to be the successor to URL, and have no rights relative to URL and the 1998 Hygrosol License Agreement, or is holding URL in the wings to file yet another redundant lawsuit once this one is dismissed. One of the core principles of *res judicata* is to prevent repeated lawsuits of the same disputes by swapping out related parties or tweaking dismissed claims.

Mutual and URL demanded judgment against Hygrosol, Dr. Spireas and the Estate of Bolton to return all of the royalties. *Id.* at ¶¶ 55, 61, 69, 77. These are the identical royalty payments that Takeda and Mutual again seek in this re-tooled federal lawsuit.<sup>12</sup>

Notably, over two (2) years ago, while pursuing the same core claims in state court, Mutual and URL sought discovery relating to the same October 2014 tax proceedings involving Dr. Spireas and the IRS, which Mutual argued supported its pending state claims against Dr. Spireas. *See* Exhibit “E” (10/20/15 Hearing Transcript) at pp. 18-29. Mutual’s and URL’s counsel, Munger, Tolles & Olson, LLP, which also represents Takeda now, specifically argued that Mutual and URL were entitled to these tax records because “[t]his is also a fraud case. I mean they defrauded us.” *Id.* at 27.

Over a year and a half before it filed its instant federal Complaint, with Count I for the same fraud claim for the same royalty payments, Mutual’s same counsel represented to the State Court that the same information from the Tax Court pleaded here at ¶¶ 17 and 64 of Takeda’s federal Complaint was necessary for its state court claims:

[D]ocuments related to two tax cases with the IRS in which Dr. Spireas and Hygrosol were involved. This pertains to income they received as a result of the license agreement that they have with Mutual, **the agreement that’s at issue here.**

We believe that depositions that may have been given or trial testimony that may have been given in those cases **about Defendants’ interpretation of the agreement** will be relevant in this case, both **to Mutual’s claims** and to Defendants’ counterclaims against Mutual in which they claim that they were

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<sup>12</sup> Much like Takeda has done here, Mutual sued Dr. Spireas, Hygrosol and the Estate of Bolton to recover these same royalties under a scattershot series of overlapping, and at times contradictory, causes of action, specifically: (1) Declaratory Judgment, (2) Breach of Contract, (3) Fraudulent Misrepresentation – Misrepresentations Made Before the Parties Signed the License Agreement, (4) Fraudulent Misrepresentation – Misrepresentations Made After the Parties Signed the License Agreement, and (5) Unjust Enrichment. *See* Exhibit “A” (*Mutual v. Spireas* Complaint).

not paid sufficient **royalties under the agreement**....

*See* Exhibit “E” at 19-20 (emphasis added). The state court refused to allow the discovery into the tax litigation, despite Mutual’s and URL’s argument that it was relevant to proving their pending claims about the royalty payments. *Id.* at 26-29.

Five (5) months later the state court dismissed Mutual’s same claims for the same royalty payments sought here by a swapped-out Takeda. *See* Exhibit “B.” The time and place to tweak any factual allegations and claims were in the state court before the claims were dismissed. That decision has now been affirmed by the Superior Court of Pennsylvania, and under Pennsylvania law, was already a final decision on the merits. *See* Exhibit “C.”

## **2. Dr. Spireas Is Currently Pursuing His Claims In State Court To Recover Royalties From Mutual.**

Dr. Spireas, Dr. Bolton, Hygrosol and SigmaPharm, jointly or, at times, separately, continued to pursue their claims against Mutual and URL for unpaid royalties.

First, in *Mutual v. Spireas*, Dr. Spireas, Hygrosol and the Estate of Bolton were Defendants in an action filed by Mutual and URL to recover the identical royalty payments which Takeda now seeks in this re-tooled federal lawsuit. Mutual’s and URL’s claims were dismissed. Dr. Spireas, Hygrosol and the Estate of Bolton, as counterclaim plaintiffs, seek to recover, *inter alia*, royalties on metaxalone generics not at issue in this federal lawsuit.<sup>13</sup> Notably, while Takeda filed this litigation as the purported successor to Mutual, Mutual remains the named counterclaim defendant in *Mutual v. Spireas*, and neither Takeda nor Mutual have made any effort or suggestion that substitution of parties is necessary or appropriate. *See* Exhibit

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<sup>13</sup> In *Mutual v. Spireas*, Dr. Spireas and Hygrosol also seek to recover through their counterclaims, *inter alia*, unpaid royalties relating to Mutual’s sublicense of certain of Hygrosol Technology and/or a SigmaPharm Innovation to a third party – King Pharmaceuticals, Inc. (“King”).

“F” for the docket in *Mutual v Spireas*. Indeed, although Takeda claims to be Mutual’s successor in this federal action, URL (not Takeda or even Mutual) continued to pay Hygrosol royalty payments on the sale of felodipine and propafenone. *See* Exhibit “G.”<sup>14</sup>

Second, in *Hygrosol v Roberts*,<sup>15</sup> Dr. Spireas and Hygrosol assert claims against Mutual and King. These tort claims relate to the contractual claims asserted in *Mutual v. Spireas* but were severed into a separate action by the state court due to the claims against King and other non-Mutual entities.

Third, in *SigmaPharm v. Mutual*,<sup>16</sup> Dr. Spireas’s other company, SigmaPharm, demands payment under the SigmaPharm Development Agreement. SigmaPharm maintains that Mutual entered into an agreement with King that Mutual would not manufacture a generic version of metaxalone based upon a SigmaPharm Innovation. In return, King paid Mutual \$35 million up front and then hundreds of millions of dollars in royalties going forward, for which fifty percent (50%) is owed to SigmaPharm.

### **3. Takeda Improperly Filed This Re-Tooled Federal Lawsuit On The Eve Of The Mediation As Leverage in the State Court Actions**

The three state court proceedings have been pending for almost six (6) years since

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<sup>14</sup> Public records reflect that Takeda owned mutual for only a matter of months in 2012 before it sold off everything except colchicine, a gout drug not at issue here, to a third party and its rights to royalties being paid by Pfizer and arising from another drug developed by Dr. Spireas. *See* Exhibit “H.” As set forth below, this Court may take judicial notice of such public records.

<sup>15</sup> *See Hygrosol Pharmaceutical Corp. and Spiridon Spireas, Ph.D. v. Richard Roberts, M.D., Ph.D., Pharmaceutical Holdings Company, Inc., Pharmaceutical IP Holdings, Inc., Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc., King Pharmaceuticals, Inc., and King Pharmaceuticals Research and Development, Inc.*, C.C.Phila., No. 12-11-00213 (“*Hygrosol v Roberts*”).

<sup>16</sup> *See SigmaPharm, Inc. v. Mutual Pharmaceutical Co., United Research Laboratories, Inc., Richard Roberts, M.D., Ph.D., Pharmaceutical IP Holdings, Inc., Pharmaceutical Holdings Company, Inc., King Pharmaceuticals, Inc., and King Pharmaceuticals Research and Development, Inc.*, C.C.Phila., No. 12-01-01176 (“*SigmaPharm v. Mutual*”).

approximately 2011, and are scheduled to be trial-ready in May 2017. In light of this advanced procedural posture, the parties agreed to attempt to mediate these three actions before the Honorable Diane Welsh and David Geronemus in February 2017. Because all of Mutual's claims had been dismissed, the only pending claims to be mediated were the claims against Mutual, URL and King and their related parties.<sup>17</sup>

On January 31, 2017, just days before the scheduled mediation, Takeda – the purported successor of Mutual – filed this federal action demanding \$150 million solely from Dr. Spireas **personally**. Takeda's federal lawsuit against Dr. Spireas merely substituted Takeda for Mutual to contrive diversity jurisdiction, and morphed the state court allegation that Dr. Spireas did not own the technology into the federal allegation that he told Mutual that Mutual was using it.

These are the same claims by the same parties in interest for the same damages that were dismissed by the state court on March 16, 2016.<sup>18</sup> See Exhibits "A" and "B."

The same day it filed this re-tooled federal lawsuit, Takeda's counsel emailed a copy of it to Dr. Spireas's counsel in the state court actions. Mutual's, URL's and Takeda's counsel stated:

Counsel – I am attaching a courtesy copy of a complaint filed today in EDPA by Takeda against Dr. Spireas. We believe this is very relevant to the upcoming mediation.

See Exhibit "I."

An hour and a half later, Mutual's counsel, which is Takeda's here, emailed the mediators of the state court actions:

I am attaching a copy of a complaint filed today in EDPA by

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<sup>17</sup> Hygrosol, Spireas and SigmaPharm, Inc. have settled their claims against King in *Hygrosol v Roberts* and in *SigmaPharm v. Mutual*. King is not a party to *Mutual v Spireas*.

<sup>18</sup> Like in *Mutual v. Spireas*, in this federal lawsuit, Takeda (as Mutual's successor) asserts numerous overlapping, duplicative and, at times, contradictory claims all to recover the same royalties: (1) Fraud/Misrepresentation, (2) Breach of Contract, (3) Breach of Duty of Loyalty, (4) Breach of Fiduciary Duty, (5) Conversion, and (6) Money Had And Received.

Takeda against Dr. Spireas. We believe it relevant to the upcoming mediation and would appreciate your forwarding it to Mr. Geronemus and Judge Welsh.

See Exhibit “J”

Thus, Takeda and its counsel immediately interjected this re-tolled federal action into the prior pending state actions for resolution, and necessarily admitted their redundancy.

### III. ARGUMENT

#### A. The Standards For Summary Judgment Require That Dr. Spireas’s Motion To Dismiss Be Granted

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A motion to dismiss pursuant to Fed R. Civ. P. 12(b)(6) tests the legal sufficiency of the pleading. To survive a motion to dismiss, a plaintiff must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While courts are required to accept all well-pleaded factual allegations as true, “merely conclusory” allegations “are not entitled to the presumption of truth.” *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 786 n.2 (3dCir.,2016). See also *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (“Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.”); *James v. City of Wilkes-Barre*, 700 F.3d 675, 679 (3dCir.,2012)( “[W]e disregard rote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements.”).

“Under the pleading regime established by *Twombly* and *Iqbal*, a court reviewing the sufficiency of a complaint must take three steps.” *Connelly*, 809 F.3d at 787. First, the court must “tak[e] note of the elements a plaintiff must plead to state a claim.” *Iqbal*, 556 U.S. at 675. Second, the court must identify allegations in the Complaint “that, **because they are no more than conclusions**, are not entitled to the assumption of truth.” *Id.* at 679. Third and finally, “[w]hen there are well-pleaded factual allegations, a court should assume their veracity **and then**



**determine whether they plausibly give rise to an entitlement to relief.”** *Id.* (emphasis added).<sup>19</sup>

Here, *res judicata* requires dismissal of the Complaint in its entirety because all of Takeda’s claims were either already specifically filed and dismissed, or they could have been. Furthermore, the factual allegations of Takeda’s Complaint are so patently implausible that they are virtually impossible.<sup>20</sup> Conspicuously absent is Mutual’s “sister company,” URL which is a necessary and indispensable litigant because it is the contracting and paying party. Additionally, all of the tort claims are barred by the statute of limitations and the gist of the action doctrine.

#### **B. Takeda’s Claims Are Barred By *Res Judicata***

As set forth above, Takeda re-filed Mutual’s Complaint personally against Dr. Spireas in federal court as leverage in state court after the state court dismissed Mutual’s claims for the recoupment of the same royalties. *See* Exhibit “B.” Takeda’s claims are therefore barred by *res judicata*.

“*Res judicata*, or claim preclusion, is a doctrine by which a former adjudication bars a later action on all or part of the claim which was the subject of the first action.” *Balent v. City of*

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<sup>19</sup> *See also Johns v. Northland Grp., Inc.*, 76 F. Supp. 3d 590, 597-602 (E.D.Pa.,2014) (dismissing the plaintiff’s claim where the plaintiff failed to allege facts to plausibly show a violation of the statute at issue); *Seifert v. Prudential Ins. Co. of Am.*, 2014 U.S. Dist. LEXIS 83168, \*14 (E.D.Pa.,2014)(dismissing claim where the plaintiff failed to plausibly establish breach of contract because offer letter clearly prohibited the plaintiff’s reliance on the oral representations the plaintiff sought to enforce); *Cave v. Potter*, 2011 U.S. Dist. LEXIS 101986, at \*25 (E.D.Pa.,2011)(dismissing the plaintiff’s claim where plaintiff failed to plausibly show discrimination based on a perceived disability).

<sup>20</sup> This Court may reject legal conclusions or factual claims that are contradicted by documents. *See Smith v. Litton Loan Servicing, LP*, 2005 U.S. Dist. LEXIS 1815, \*18 (E.D.Pa.,2005) (facts alleged are not deemed true for purposes of motion to dismiss when contradicted by judicially noticed facts); *Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 879 & n.3 (1st Cir. 1991)(plaintiffs had no claim for fraud in light of statements in prospectus). Accordingly, this Court may consider all of the documents attached to this Motion to Dismiss without converting this motion to one for summary judgment. *Hotel Employees & Restaurant Employees Internat’l Union v. Stadium Hotel Partners, L.P.*, 1994 WL 585707, at \*2 (E.D.Pa.,1994).

*Wilkes-Barre*, 669 A.2d 309, 313 (Pa.1995)(citing *Allen v. McCurry*, 449 U.S. 90, 94 (1980)). “Any final, valid judgment on the merits by a court of competent jurisdiction precludes any future suit between the parties **or their privies** on the same cause of action.” *Id.* (citation omitted; emphasis added).<sup>21</sup>

The purpose of *res judicata* is to “minimize judicial energy devoted to individual cases, establish certainty and respect for court judgments, and protect the party relying on the prior adjudication from the vexatious litigation.” *Heimbecker v. 555 Assocs.*, 2003 U.S. Dist. LEXIS 6636, \*33 (E.D.Pa.,2003), *aff’d without op.* 90 Fed.Appx. 435 (3dCir.,2004). “Given this purpose, the doctrine of *res judicata* must be liberally construed and applied without technical restriction.” *Id.* at \*34. *See also Balent*, 669 A.2d at 315 (purpose is to relieve parties of cost and vexation of multiple lawsuits, conserve judicial resources, prevent inconsistent decisions, and encourage reliance on adjudications).

*Res judicata* applies to bar a subsequent action where, as here, the two suits share the same four conditions: “(1) the thing sued upon or for; (2) the cause of action; (3) the persons and parties to the action; and (4) the capacity of the parties to sue or be sued.” *Turner v. Crawford Square Apts. III, L.P.*, 449 F.3d 542, 548 (3d Cir. 2006)(finding claim precluded).

**1. The Thing Sued Upon Is The Same For Purposes Of Satisfying The First Condition of *Res Judicata*.**

Takeda demands the same royalties from the sale of felodipine and propafenone as Mutual sought, unsuccessfully, in *Mutual v. Spireas*. In the underlying *Mutual v. Spireas* action, Mutual alleged that “[it] developed and sold two Products, Felodipine and Propafenone, that

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<sup>21</sup> Pennsylvania *res judicata* law applies because this is a diversity case and the Court is asked to analyze the impact of a state court judgment. *See, e.g., Jett v. Beech Interplex, Inc.*, 2004 U.S. Dist. LEXIS 13352, \*8 n.10 (E.D.Pa.,2004). “A federal court must give the same preclusive effect to a state court judgment as would be given that judgment under the law of the state in which it was rendered.” *Id.* (citation omitted).

were subject to the License Agreement” and that “between 2002 and 2011, Mutual paid approximately \$146 million under the License Agreement.” *See* Exhibit “A,” *Mutual v. Spireas* Complaint, at ¶¶ 38-39. Mutual also alleged that it continued to pay Hygrosol under the License Agreement while it litigated its claims. *Id.* at ¶41. Mutual demanded a return of all of the royalties paid to Hygrosol, i.e., \$146 million, plus additional amounts and interest. *Id.* at ¶¶ 55, 61, 69, 77.

Takeda now seeks the exact same royalty payments in this litigation. Specifically, Takeda avers that “[f]rom 2002 through 2012, Mutual paid Hygrosol approximately \$3.7 million in propafenone royalties and \$146.4 million in felodipine royalties.” (Complaint, ¶59.) Takeda demands, through its various counts, repayment of all of these same royalties. *See id.* at, e.g., ¶¶ 94 and Count I *ad damnum*.

## 2. The Cause of Action Is The Same For Purposes Of Satisfying The Second Condition of *Res Judicata*.

*Res judicata* bars re-litigation of claims that were actually raised in a prior proceeding, and also claims **that could have been but were not raised in a prior proceeding.** *Heimbecker*, 2003 U.S. Dist. LEXIS 6636, at \*33. *See also 3G Wireless, Inc. v. Metro PCS Pa. LLC*, 2016 U.S. Dist. LEXIS 24283, at \*17 (E.D.Pa.,2016) (finding addition of new parties “[did] not save the case” and barring claims that were based on some additional facts, as they were substantially similar claims to those brought in the prior proceeding).

Thus, the identity of “the cause of action” does not require that the same cause of action actually be pled. This prevents a party, like Takeda, from “repackaging” the same claim under a different “cause of action” in a veiled effort to re-litigate the same dispute. *See Miller v. Comm., Bd. of Property*, 533 A.2d 819, 820-21 (Pa.Comm.w.,1987).

It is well settled Pennsylvania law that “*res judicata* will not be ‘defeated by minor

differences of form, parties, or allegations, when these are contrived only to obscure the real purpose [of the second litigation], – a second trial on the same cause between the same parties.” *Tobias v. Halifax Twp.*, 28 A.3d 223, 226 (Pa.Commw.,2011)(barring claims that plaintiff should have raised in first litigation between parties); *see also Centrix HR, LLC v. On-Site Staff Mgmt., Inc.*, 2014 Phila. Ct. Com. Pl. LEXIS 123, \*11-12 (C.C.P.,2014) (finding second lawsuit barred by *res judicata* when different plaintiff was sole shareholder of corporation which brought first action).

“A party cannot evade the doctrine of claim preclusion by asserting different rights arising from the same transaction or series of connected transactions that gave rise to the initial lawsuit.” *Stout v. Am. Federation of State*, 2009 U.S. Dist. LEXIS 130725, \*14-15 (E.D.Pa.,2009)(barring claims where plaintiff asserted different claims arising under same theory that defendant failed to pay plaintiff amount owed). *See also Centrix HR, LLC*, 2014 Phila. Ct. Com. Pl. LEXIS 123 at \*11-12 (barring claims and finding first two elements of *res judicata* satisfied where plaintiffs were “seeking the same relief for breach of contract based upon the same contracts that were at issue in the federal lawsuit”).

“Claim preclusion would be a toothless doctrine if plaintiffs could circumvent the doctrine by asserting an identical claim under a different name.” *Stout*, 2009 U.S. Dist. LEXIS 130725 at \*12.

In both *Mutual v. Spireas* and the re-tooled instant federal action, *Takeda v. Spireas*, the affiliated plaintiffs (Mutual and Takeda) accuse Dr. Spireas of engaging in misconduct intended to induce Mutual to pay him contractual royalties on the propafenone and felodipine generic drugs. In both of these cases, the plaintiffs (Mutual and Takeda) contorted the same redundant, shotgun and, at times contradictory, theories upon which they demand payment of the exact same

royalties. Mutual's claims, which it intended to support with testimony from the tax court, were dismissed by the Philadelphia Court of Common Pleas. *See* Exhibit "B." Takeda now attempts, in bad faith, to continue to try to recover those royalties by once again alleging misconduct against Dr. Spireas, but now desperately tweaked as being premised upon an out-of-context "inaudible" and "scratched" snippet from the tax court. Takeda's redundant and vexatious action is barred by the doctrine *res judicata*.<sup>22</sup>

During the course of litigating its claims, Mutual and URL sought discovery from Dr. Spireas relating to tax proceedings involving him and the IRS. *See* Exhibit "E" (Hearing Transcript) at pp. 18-29. Mutual's and URL's counsel, who also represents Takeda, explained that they were seeking:

[D]ocuments related to two tax cases with the IRS in which Dr. Spireas and Hygrosol were involved. This pertains to income they received as a result of the license agreement that they have with Mutual, **the agreement that's at issue here.**

We believe that depositions that may have been given **or trial testimony** that may have been given in those cases **about Defendants' interpretation of the agreement** will be relevant in this case, both **to Mutual's claims** and to Defendants' counterclaims against Mutual in which they claim that they were not paid sufficient royalties under the agreement.

*See* Exhibit "E" at 17-19 (emphasis added).

Significantly, Mutual's counsel pointedly asserted that the tax case testimony was

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<sup>22</sup> In *Mutual v. Spireas*, Mutual alleged that Dr. Spireas, Dr. Bolton and Hygrosol "fraudulently schemed to accomplish their goal of getting Mutual to enter into, and perform under, the license Agreement, and the scheme consisted of at least two interrelated parts." *See* Exhibit "A" (*Mutual v. Spireas* Complaint) at ¶ 23. In the first part of this multipart "scheme," Mutual alleges that "Defendants knowingly, purposefully and willfully misrepresented to Mutual that they owned the Patents and the Technology in order to induce Mutual to enter into the License Agreement." *Id.* In the second part, Mutual alleges, "after the parties entered into the License Agreement, Defendants repeatedly made misrepresentations in order to conceal their breaches of the License Agreement so that Mutual would continue the contractual relationship and fail to assert its contractual rights against Defendants." *Id.*

relevant because: **“This is also a fraud case. I mean they defrauded us.”** *Id.* at 27 (emphasis added). In other words, it was Mutual’s express intent to utilize the tax court proceedings to support its various multi-part claims then pending in *Mutual v. Spireas*.<sup>23</sup>

The claims in both cases are the same. Slightly tweaking an underlying factual basis or re-naming a cause of action for the same claims does not change them. Both the state and federal Complaints assert that Dr. Spireas improperly induced Mutual to pay Hygrosol royalties on the propafenone and felodipine generic drugs in violation of his contractual and employment duties. The damages are also the same. As such, the second condition for *res judicata* is satisfied.

### **3. The Parties And Their Capacities Are The Same For Purposes Of Satisfying The Third And Fourth Conditions of *Res Judicata*.**

Takeda filed the instant action as the purported successor to Mutual and is pursuing Mutual’s rights under the 1998 Hygrosol License Agreement, just as Mutual pursued them, unsuccessfully in *Mutual v. Spireas*. Indeed, Takeda literally pleads that: “It is the successor-in-interest to Mutual.” (Complaint, ¶1.) This satisfies the third and fourth conditions of *res judicata*. See *Jett v. Beech Interplex, Inc.*, 2004 U.S. Dist. LEXIS 13352, at \*13 (E.D.Pa.,2004)(applying Pennsylvania *res judicata* law to hold that identity of parties is satisfied when the relationship between entities or individuals is close enough that the non-party’s interests were represented in the prior action).<sup>24</sup>

Thus, all four elements of *res judicata* apply. They are the identical claims for the

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<sup>23</sup> Mutual admittedly knew about Dr. Spireas’s tax testimony prior to the dismissal of its claims against him five (5) months later, and it is, therefore, a claim that “could have been brought” by Mutual against Dr. Spireas in the existing *Mutual v. Spireas* action. *Balent*, 669 A.2d at 313.

<sup>24</sup> Takeda’s counsel also further conceded that the parties are the same as between this action and *Mutual v. Spireas*. See Statement of Non-Opposition to Defendant’s Motion for an Extension of Time to Respond to Plaintiff’s Complaint (Doc. 6) at 2.

identical damages by the identical parties in their identical capacities. *Res judicata* bars the claims.<sup>25</sup>

**C. Whether Characterized As Tort Or Breach, Takeda’s Federal Complaint That Dr. Spireas Perpetrated A Fraud On Mutual And/Or That Mutual Did Not Know The Formulations It Used To Subsequently Manufacture And Sell Drugs For More Than A Decade Is Unsupportable And Implausible**

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Takeda claims that Dr. Spireas “perpetrated a massive fraud on Mutual,” because, contrary to Dr. Spireas’s representations, “the generic felodipine and propafenone formulations he developed for Mutual, which were the basis for the royalties that Mutual paid to him and Bolton, were not actually developed using the patented liquisolid technology.” (Complaint, ¶ 17.) However, it is clear beyond dispute why Takeda and Mutual failed over ten years to discover this so-called “massive fraud” – because it never occurred.

In this regard, the felodipine and propafenone drug products are either manufactured using steps identified in the allowed claims in one of the four liquisolid patents, or they are not. (Complaint, ¶¶32-34.) Extraordinarily strict federal law controls the manufacturing process.

Indeed, the Food, Drug, and Cosmetic Act provides that “[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application...is effective with respect to such drug.” 21 U.S.C. § 355(a). Mutual manufactured felodipine and propafenone pills – billions of them – in its Philadelphia drug factory, knowing that the drugs would be distributed and sold to consumers with serious medical conditions. In order to get permission to sell the drugs, it was required to file applications with the FDA that

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<sup>25</sup> Collateral estoppel also bars the re-tooled Takeda federal action. “Collateral estoppel, or issue preclusion, is a doctrine which prevents re-litigation of an issue in a later action, **despite the fact that it is based on a cause of action different from the one previously litigated.**” *Balent*, 669 A.2d at 313 (emphasis added). All of these claims and issues were litigated and dismissed by the state court. They are barred by claim preclusion (*res judicata*) and by issue preclusion (*collateral estoppel*).

included specific and detailed information regarding the manufacturing process, which could not be changed without FDA permission. *See* 21 C.F.R. § 210.1(a) (FDA regulates the manufacturing, processing, packing, and holding of a drug through its Current Good Manufacturing Practice (“CGMP”) regulations). During the entire time Mutual made felodipine and propafenone, its employees were required to follow precise formulas giving them instructions on each and every step. *See* 21 C.F.R. § 210.1(b) (failure to comply with the CGMP regulations renders the drug at issue “adulterated,” and such drug, and the persons responsible for the failure to comply with the CGMP regulations, shall be subject to regulatory action).

Each liquisolid patent describes methods by which water insoluble drug or nutritional products might be formulated as pills or capsules that can be easily ingested by consumers.<sup>26</sup> While an end-user might not be able to determine whether the patented processes were involved in making the drug, the drug maker itself would not only know, but would be applying such processes every day and in the manufacture of every pill. It is required by law to do so. *E.g.*, 21 C.F.R. § 210.1(a)(b).

Mutual retained Hygrosol by a Letter Agreement dated March 7, 2000, which Takeda

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<sup>26</sup> Each of the four patents described in Takeda’s Complaint can be viewed by copying and pasting into a browser the following:

<http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetacgi%2FPTO%2Fsearch-bool.html&r=16&f=G&l=50&co1=AND&d=PTXT&s1=liquisolid&OS=liquisolid&RS=liquisolid;>

<http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetacgi%2FPTO%2Fsearch-bool.html&r=15&f=G&l=50&co1=AND&d=PTXT&s1=liquisolid&OS=liquisolid&RS=liquisolid;>

<http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetacgi%2FPTO%2Fsearch-bool.html&r=14&f=G&l=50&co1=AND&d=PTXT&s1=liquisolid&OS=liquisolid&RS=liquisolid;>

[http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetacgi%2FPTO%2Fsearch-bool.html&r=13&f=G&l=50&co1=AND&d=PTXT&s1=liquisolid&OS=liquisolid&RS=liquisolid.](http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnetacgi%2FPTO%2Fsearch-bool.html&r=13&f=G&l=50&co1=AND&d=PTXT&s1=liquisolid&OS=liquisolid&RS=liquisolid;)



attaches as Exhibit B to its Complaint. Mutual fired Dr. Spireas in 2004. (Complaint, ¶54.) Mutual started selling generic propafenone in 2001 and generic felodipine in 2004. (Complaint, ¶¶ 57, 58.) Mutual made its first royalty payment to Spireas and Bolton on generic felodipine sales in the first quarter of 2002, and made its first royalty payments to Spireas and Bolton on generic felodipine sales in the fourth quarter of 2004. *Id.*

Takeda's Complaint artfully pleads that Dr. Spireas allegedly told Mutual that Mutual was using patented liquisolid technology:

48. Spireas consistently *represented* to Mutual that the generic felodipine and propafenone formulations in the felodipine and propafenone ANDA submissions used the patented liquisolid technology. [<sup>27</sup>]

Despite this allegation, Mutual manufactured propafenone for ten years and felodipine for six years and therefore had actual knowledge that the manufacturing process used the patented liquisolid technology (triggering the royalty obligations under the License Agreement) no matter what Dr. Spireas allegedly said a decade later during a 2014 tax trial.

Indeed, conspicuously absent from Takeda's Complaint is an averment that none of the Hygrosol Technology was utilized. *See* Complaint (Doc. 1) *passim*. This omission is not a mere oversight. In fact, the opposite is true. In Paragraph 75, Takeda admits that there are, at least, "small amounts of nonvolatile solvent in the felodipine and propafenone formulations that [Dr. Spireas] developed for Mutual..." *Id.* at ¶ 75. In that same Paragraph, Takeda admits that the Hygrosol Technology "rel[ies] on the use of 'nonvolatile' solvents." *Id.* The inclusion of such solvents is a hallmark and indicator of the use of the Hygrosol Technology. In other words, Takeda scoured Mutual's records on the formulation of these drugs, which Mutual has been

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<sup>27</sup> The only specific statements by Dr. Spireas identified by Takeda allegedly occurred in three (3) formal scientific reports in 2000, well before Mutual made and sold the drugs at issue in the Complaint. (Complaint, ¶¶48-58.)

manufacturing for more than a decade, and concluded that in fact the Hygrosol Technology was, at least to some extent, utilized in these formulations. Recognizing the fatal impact of this necessary admission, Takeda pivots without support and alleges that “[t]here was no legitimate purpose to the inclusion of the nonvolatile solvents other than to deceive Mutual.” *Id.* This fails the heightened pleading requirement of Fed.R.Civ.P. 9(b).

In fact, Mutual’s own actions at the time further belie its fabricated 2017 federal allegations. After Mutual submitted its ANDA for felodipine, it spent years defending Dr. Spireas’s formulation against a challenge by AstraZeneca, which claimed that Mutual’s formulation violated the patented AstraZeneca process used on its drug, Plendil. *See, e.g., AstraZeneca AB v. Mutual Pharmaceutical Co., Inc.*, 278 F.Supp.2d 491 (E.D.Pa.,2003), *reversed* in favor of Mutual at 384 F.3d 1333 (Fed.Cir.,2004).

During and before the *AstraZeneca* lawsuit, Mutual submitted Dr. Spireas’s formulation to two law firms for opinion letters and caused it to be scrutinized by multiple experts in order to establish that the drug made using Dr. Spireas’s patented liquisolid process was an invention that did not infringe on the AstraZeneca process patent. *See AstraZeneca AB*, 278 F.Supp.2d at 520 (discussing formulation and confirming Mutual’s reliance on experts).<sup>28</sup>

In the *AstraZeneca* lawsuit, Mutual’s felodipine drug was found not to infringe on

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<sup>28</sup> Notably, Takeda falsely alleges that Mutual blindly relied upon Dr. Spireas’s representation from 2000 as it paid Hygrosol \$150 million over the course of a decade, including during even the first year of the state court lawsuit, *Mutual v Spireas*. (Complaint, ¶56.) Takeda claims that it was justified in doing so, because Dr. Spireas was Mutual’s “only expert in the technology” and the “senior scientific executive of the company.” *Id.* As noted above, Takeda’s allegation is patently false in light of Mutual’s reliance upon two separate experts in the *AstraZeneca* litigation. Moreover, Takeda admittedly fired Dr. Spireas in 2004 before it obtained final approval to market felodipine (which accounts for approximately 98% of the royalties at issue). (Complaint, ¶¶54, 58-59.) Therefore, contrary to Takeda’s allegations, Dr. Spireas was not the “senior scientific executive” at the time Mutual began manufacturing and selling that drug – he wasn’t even an employee.

AstraZeneca's patent because Mutual's felodipine drug was formulated using the general techniques in Dr. Spireas's '339 Patent. *See AstraZeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339-1340 (Fed.Cir.,2004). Mutual immediately began selling the felodipine drug formulated by Dr. Spireas and received over a billion dollars in revenues.<sup>29</sup>

This is not fraud, tort or breach. It is an absurdity. It was Mutual that made these generic drugs in its own facility, then sold them to the public and paid Hygrosol royalties after successfully defending its right to do so against AstraZeneca. Dr. Spireas was not even employed at Mutual during the years it manufactured felodipine and was mostly absent while it manufactured propafenone. (Complaint, ¶ 54.)

**D. Takeda's Complaint Must Be Dismissed For Failure To Join An Indispensable Party**

Federal Rule of Civil Procedure Rule 12(b)(7) provides the grounds for a motion to dismiss for "failure to join a party under Rule 19." A Rule 19 inquiry is bifurcated. *Guthrie Clinic, Ltd. v. Travelers Indem. Co.*, 104 Fed.App'x 218, 221 (3dCir.,2004). First, under Rule 19(a), a court considers whether a party is "necessary" to an action. *Id.* If a party is deemed necessary, then joinder must occur if feasible. *Id.*; *see also* Fed. R. Civ. P. 19(a),(c). If, on the other hand, "the addition of a necessary party would divest a court of subject matter jurisdiction, then a court must determine whether in 'equity and good conscience' the action should proceed without that party, or whether the action should be dismissed, 'the absent person being thus

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<sup>29</sup> Dr. Spireas' felodipine formulation used a non-volatile liquid called propylene glycol 400 ("PEG 400") as one of the co-solvents used to dissolve felodipine and create the mixture described in Claim 1(a) of the '339 Patent. In fact, dependent Claim 10 actually identifies propylene glycol as one of the liquids that might be used to dissolve the pharmaceutical ingredient as part of the step described in Claim 1(a). AstraZeneca's patent used a like non-volatile liquid but only as a surfactant. Because of this, the Federal Circuit concluded that the felodipine formula developed by Dr. Spireas (the inventor) did not infringe AstraZeneca's patent. *See AstraZeneca*, 384 F.3d at 1339-1340.

regarded as indispensable.” *Guthrie*, 104 Fed.App’x at 221. Under controlling Third Circuit precedent “a finding of indispensability under Rule 19(b) necessitates dismissal for lack of subject matter jurisdiction.” *Id.*

**1. URL Is A Necessary Party Under Rule 19(a).**

“It is well-established that a party to a contract which is the subject of the litigation is considered a necessary party.... In a breach of contract claim, all parties to the contract should ordinarily be joined.” *See Mattia v. Allstate Ins. Co.*, 2014 U.S. Dist. LEXIS 86258, at \*13 (E.D.Pa.,2014); *see also Rashid v. Kite*, 957 F. Supp. 70, 74 (E.D.Pa.,1997)(same).

Here, Takeda filed suit against Dr. Spireas for breach of contract and a collection of overlapping and largely redundant tort and quasi-contract claims all relating to the 1998 Hygrosol License Agreement, which Takeda attaches as Exhibit A to its Complaint. Takeda claims to have standing to bring this suit as the successor in interest to Mutual. However, Takeda admits as it must that Mutual is not the only party to the 1998 Hygrosol License Agreement; instead, Mutual’s “sister company, United Research Laboratories, Inc. . . .” is also a party. (Complaint, ¶18, Ex.A, intro.) Therefore, as a party to the contract, URL is a necessary party pursuant to Rule 19(a)(1) that must be joined if feasible. *Mattia*, 2014 U.S. Dist. LEXIS 86258, at \*13; *Rashid*, 957 F. Supp. at 74.<sup>30</sup>

Mutual cannot avoid the plain terms of the 1998 Hygrosol License Agreement or its

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<sup>30</sup> Recognizing this inevitability, Takeda attempts to mislead the Court by averring that it alone had exclusive rights and interests to the intellectual property, the Products, and the other provisions of the 1998 Hygrosol License Agreement. (Complaint, ¶25 (citing Complaint Ex.A §2.1).) Takeda’s averment is directly contradicted by the plain reading of the 1998 Hygrosol License Agreement. In fact, the very first sentence of §2.1 states: “Spireas, Bolton and Hygrosol grant to Mutual and United: ...The exclusive rights to utilize the Technology...[and] The exclusive right to produce, market, sell, promote and distribute...said Products...” (Complaint, Ex.A ¶2.1.) Section 2.2 then reaffirms that “Mutual and United shall have the exclusive right to Produce and Sell the Products...” *Id.* at ¶ 2.2.

consequences. URL is a fully executed party to it, and Takeda is attempting to re-litigate Mutual's and URL's purported rights under that Agreement with the very practical impact of impeding or impairing any rights that URL might have under it. This is exactly what Rule 19(a), by its express terms, prohibits.

**2. URL Cannot Be Joined Because It Would Defeat Jurisdiction.**

URL is registered with the Pennsylvania Department of State as a domestic business corporation located in Philadelphia. *See* Exhibit “K.” According to SunPharma’s publically available financial records, URL was merged in 2015 with Mutual (another subsidiary of SunPharma) and continues its manufacturing in Philadelphia, Pennsylvania. *See* Exhibit “L.” For purposes of diversity jurisdiction, at least as a result of its manufacturing activities, it is deemed to be domiciled in Philadelphia, Pennsylvania, and not diverse with Dr. Spireas. URL’s joinder would, therefore, defeat the diversity jurisdiction of this Court, which is the sole basis for jurisdiction. *See* Complaint at ¶ 3 (asserting subject matter jurisdiction under 28 U.S.C. §1332, because there is complete diversity between Takeda (DE and IL) and Dr. Spireas (PA)). *See Guthrie Clinic Ltd.*, 104 Fed.App’x at 223 (finding dismissal appropriate where insurance company’s broker was non-diverse indispensable party); *Crown Cork & Seal Co. v. Continental Holdings*, 1994 U.S. Dist. LEXIS 13956, at \*17 (E.D.Pa.,1994)(dismissing plaintiff’s claim as necessary party would destroy diversity jurisdiction); *Angst v. Royal Maccabees Life Ins. Co.*, 77 F.3d 701, 706-07 (3dCir.,1996)(dismissing plaintiff’s claims as the non-diverse intervenor was an indispensable party). Takeda’s, Mutual’s and URL’s counsel did not name URL as a plaintiff because it would have destroyed diversity and put them right back in front of the same state court that already dismissed their same claims.

### 3. **This Action Must Be Dismissed Pursuant To Rule 19(b).**

URL is also an *indispensable* party. Rule 19(b) provides certain considerations for the court in determining whether in “equity and good conscience” the action should proceed without URL, or whether the action should be dismissed. *See* Fed. R. Civ. P. 19(b); *Guthrie*, 104 Fed.App’x at 221. Rule 19(b) sets forth the following considerations:

- (1) the extent to which a judgment rendered in the person’s absence might prejudice that person or the existing parties;
- (2) the extent to which any prejudice could be lessened or avoided by: (A) protective provisions in the judgment; (B) shaping the relief; or (C) other measures;
- (3) whether a judgment rendered in the person’s absence would be adequate; and
- (4) whether the plaintiff would have an adequate remedy if the action were dismissed for nonjoinder.

Fed. R. Civ. P. 19(b)(1)-(4). These factors require dismissal.

With respect to the first factor, the analysis largely overlaps with the Rule 19(a) analysis. *Wilson*, 2009 U.S. Dist. LEXIS 16714, at \*29. As discussed above, URL is a party to the 1998 Hygrosol License Agreement with the same “exclusive rights” to the same products that Takeda now seeks to adjudicate in this litigation. (Complaint, Ex.A, §§ 2.1, 2.2.) Yet, URL is not a party to this lawsuit. Mutual, and therefore Takeda, certainly understand URL’s status as a party to the 1998 Hygrosol License Agreement with corresponding rights, because when Mutual last sued Dr. Spireas to recover these same exact royalties on these same exact drugs, the complaint was filed by **both Mutual and URL**. *See* Exhibit “A.” Though they lost that case, Mutual demonstrated its proper understanding of the law – that URL was also a necessary plaintiff when trying to adjudicate rights under and relating to the same contract. Here, Takeda improperly disregards this “well-established” legal requirement to manufacture diversity jurisdiction.

The prejudice to URL in proceeding without it in this litigation concerning its contract rights is severe. *See Guthrie Clinic*, 104 Fed.App'x at 223 (holding that the potential that any adverse judgment or finding could be held against the absent party in another forum supported dismissal under the first consideration).<sup>31</sup>

The second and third Rule 19(b) considerations, of whether the impact of this prejudice can be lessened in any way, and whether a judgment entered in the contracting party's absence would be adequate, are "closely linked" and so are appropriately addressed together. *See Guthrie Clinic*, 104 Fed.App'x at 223. Simply put, there is no precaution or safeguard that can be put in place and afford adequate relief to the litigation parties without URL as a party. Though Takeda tries to limit its damages to end in 2012, so as not to infringe upon URL's rights, or SunPharma's damages, the issues that must be decided in order to award damages will directly adjudicate URL's rights under the 1998 Hygrosol License Agreement. A judgment in this case necessarily

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<sup>31</sup> It is important to note that Takeda does not plead that it is URL's successor and, in fact, the public record confirms that it is not. Instead, though Takeda initially acquired URL at the time it acquired Mutual, Takeda sold URL (and at least some portion of Mutual) within months of its acquisition. *See* Exhibit "H." Public records also reveal that Takeda purchased Mutual and URL only to create a monopoly on one drug owned by Mutual, which is not at issue in this lawsuit, and sold the generic drugs that are at issue in this lawsuit to SunPharma by the end of 2012. *Id.* Takeda confirms this in its Complaint by deceptively trying to artificially tailor its damages to only the period of time before it made the sale to SunPharma. Specifically, Takeda admits that the \$150 million at issue is limited only to the time frame between 2002 through 2012, i.e., the year Takeda sold URL and most of Mutual to Sun. *See* Complaint, ¶59 (limiting royalty payments to "2002 through 2012"). Takeda cannot avoid the impact of this litigation concerning URL's exclusives rights by artificially trying to limit its damages to only a window of time when it believes it previously owned these generic drugs. Instead, the Court's determination of "exclusive rights" to these drugs will necessarily directly impact URL and its current ownership rights to these drugs. Indeed, Takeda's artificial limitation on damages to only cover damages through 2012, though additional royalties were paid by Mutual after 2012, undermines Takeda's unsupported and unexplained assertion that it is the "successor to Mutual." It is apparent that while Takeda claims to have been Mutual's successor to some extent, it is not Mutual's complete successor because it does not have Mutual's rights after 2012. This causes serious concerns about Takeda's professed standing to bring suit, which is a jurisdictional issue that requires threshold discovery should this Court not dismiss the entire action, which it should do.

requires a determination of Mutual's and URL's rights to the Products relative to Dr. Spireas, Mutual and URL under the 1998 Hygrosol License Agreement. Either the Hygrosol Technology was used, or it was not. That finding cannot change in subsequent actions and no relief can be afforded in this litigation without making that determination, which, by the terms of the Agreement, impacts URL. *See Guthrie Clinic, Ltd.*, 104 Fed.App'x at 223.

The fourth Rule 19(b) consideration of whether the plaintiff would have an adequate remedy if the action were dismissed for nonjoinder is significant, and an issue that some courts have found alone to be dispositive. *See Guthrie Clinic*, 104 Fed.App'x at 222-23. Here, the contracting parties in the 1998 Hygrosol License Agreement all agreed to litigate any disputes in the state and federal courts of Pennsylvania. (Complaint, Ex.A, §13.) Therefore, the state court, **where all the contracting parties are currently litigating**, provides an adequate remedy. Accordingly, this case must be dismissed for Takeda's failure to join URL. *Wilson*, 2009 U.S. Dist. LEXIS 16714, at \*36; *Crown Cork & Seal Co.* 1994 U.S. Dist. LEXIS 13956, at \*17 (explaining identical action with all interested parties could be maintained in state court and "it is difficult to perceive the structuring of this lawsuit as other than an attempt to contrive federal jurisdiction or otherwise expose defendants to the risk of further litigation of the same issues"); *Angst*, 77 F.3d at 706 (finding fourth factor in Rule 19 analysis was dispositive since plaintiff's action could be maintained against all parties in state court).<sup>32</sup>

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<sup>32</sup> Indeed, as Mutual already demonstrated, it knows it can file suit against Dr. Spireas in state court. It is transparently obvious that the reason that this suit was not filed in that court, which is much more familiar with the parties and the facts surrounding these agreements and claims, is because Mutual and URL both already lost their efforts to recover the same royalties that Takeda now redundantly seeks in this lawsuit. This is not a reason, however, that the case cannot, and should not, have been brought in state court – it just demonstrates Takeda's reasons for excluding URL in order to manufacture diversity jurisdiction. This action could be, and should have been, *and was*, brought in state court. *See* Exhibits "A," "B," "C," "E" and "F."



**E. All Claims Except For Takeda's Breach Of Contract Claim In Count II Are Barred By The Statute Of Limitations**

Takeda's claims are clearly barred by the statute of limitations, except for Count II, which must also be dismissed for the other reasons set forth in this Memorandum.

The only allegations against Dr. Spireas relate to three formal reports from 2000. (Complaint, ¶¶48-58.) That was seventeen (17) years ago. Mutual fired Dr. Spireas in 2004. (Complaint, ¶54.) That was thirteen (13) years ago. Mutual sued Dr. Spireas for the same claims in 2011, which were dismissed. *See* Exhibits "A" and "B." That was six (6) years ago.

Seventeen (17) years after any alleged misrepresentation, thirteen years after it fired Dr. Spireas, and six (6) years after it sued Dr. Spireas, Takeda filed this redundant and frivolous lawsuit. The statute of limitations begins to run at "the time the cause of action accrued." 42 Pa. Cons. Stat. § 5502(a). All claims other than for breach of contract in Count II are barred by the two year statute of limitations. 42 Pa. Cons. Stat. § 5524(7).<sup>33</sup>

The Third Circuit has recognized that "the statute of limitations can serve as the basis for dismissal under Fed. R. Civ. P. 12(b)(6), as long as the time alleged in the statement of a claim shows that the cause of action has not been brought within the statute of limitations." *Hawk Mt. LLC v. Mirra*, 2016 U.S. Dist. LEXIS 72962 (D.Del.,2016)(doctrine of equitable tolling does not apply because record establishes that plaintiffs filed the complaint more than four years after

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<sup>33</sup> Takeda pleads in ¶¶22-24 the legal conclusion that the 20 year statute of limitations for contracts under seal applies to its breach of contract claim against Dr. Spireas in this federal action under 42 Pa. Cons. Stat. § 5529. However, despite the plain language of the 1998 Hygrosol License Agreement immediately above all of the signatures, Takeda, Mutual and URL assert in the state court actions that the 4 year statute of limitations under 42 Pa. Cons. Stat. § 5525(a)(8) applies to any breach of contract claim against them. Thus, this precise issue is being litigated in state court between all of the contracting parties to the 1998 Hygrosol License Agreement, after years of discovery. This also demonstrates why URL is an indispensable party to the same dispute here, and why this case must be dismissed to be litigated in state court, where the identical parties and identical issues are already pending.

being on inquiry notice of actionable claims)(quoting *McPherson v. United States*, 392 Fed.App’x 938, 943 (3dCir.,2010)). The Third Circuit “appl[ies] **an injury discovery rule** whereby a...claim accrues when plaintiffs knew **or should have known of their injury.**” *Id.* (emphasis added)(citing *Cetel v. Kirwan Fin. Grp., Inc.*, 460 F.3d 494, 507 (3dCir.,2006)). “A cause of action accrues for statute of limitations purposes when the plaintiff knows or has reason to know **of the injury** that constitutes the basis of the cause of action.” *McCool v. Snyder County*, 2014 U.S. Dist. LEXIS 88834, \*23, 2014 WL 2930648 (M.D. Pa. June 27, 2014)(emphasis added).

No tolling doctrine can resurrect a 17 year old claim after years of multiple litigations. Clearly, Mutual – and therefore Takeda – knew about its purported *injury* when it sued Dr. Spireas for the same damages under the same contract in 2011. *See* Exhibit “A.” Takeda fatally fails to plead any facts to show how, when and why it was prevented from determining that it had been injured after Dr. Spireas was no longer an employee in 2004, after it defended claims by AstraZeneca, and after it sued Dr. Spireas for the same damages under the same contract in 2011. *United States ex rel. Liberty Mech. Servs. v. N. Am. Specialty Ins. Co.*, 2 F.Supp.3d 610 (E.D.Pa.,2014)(motion to dismiss granted because complaint did not contain sufficient well-pleaded facts to support equitable tolling). *See also Southern Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group, Ltd.*, 181 F.3d 410 (3dCir.,1999)(“It follows that they should have known all the information sufficient to begin the running of the statute of limitations...”); *In re Merck & Co., Inc. Sec. Litig.*, 2004 U.S. Dist. LEXIS 28930, \*54 (D.N.J.,2004)(existence of a pending litigation also may be considered in determining whether inquiry notice has attached).<sup>34</sup>

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<sup>34</sup> Allegations of new misrepresentations do not trigger the rule, as “continuing efforts to conceal the initial fraud...[are] not separate and distinct fraudulent acts resulting in new and independent injuries.” *Weiss v. Bank of Am. Corp.*, 2016 U.S. Dist. LEXIS 161665, 2016 WL 6879566

Although decided at the summary judgment stage, the reasoning applied by the Honorable Franklin S. Van Antwerpen, while presiding as a District Court judge, is equally applicable:

Plaintiffs have shown no evidence of any lulling, fraud, or concealment by Defendants, intentional or not. Plaintiffs were aware of their right to sue immediately upon the alleged breach; they demonstrated this by filing two suits, a mechanic's lien and a breach of contract suit, in state court within the time limit. Rather than misleading or lulling, Defendants very appropriately argued these lawsuits, and eventually had them dismissed for non pros. In fact, it appears to us that Plaintiffs only filed suit in federal court after their attempts at resolution in state court had failed and Defendants had moved out of state thereby creating diversity. Certainly, Plaintiffs were fully cognizant of their ability to bring suit in state court. The unavailing nature of those suits does not toll the statute of limitations.

*Hatchard v. Dipalma*, 1997 U.S. Dist. LEXIS 4166; 1997 WL 164238 (E.D.Pa.,1997).

Thus, Counts, I, III, IV, V and VI are all barred by the statute of limitations. Additionally, as more fully set forth above and below, Count II must also be dismissed for failure to state a claim because it is implausible, it is barred by *res judicata*, and for failure to join an indispensable party – namely the other contracting party and “sister company,” URL.

**F. All Claims Except For Takeda's Breach Of Contract Claim In Count II Are Barred By The Gist Of The Action Doctrine**

To the extent the Court concludes that any tort or quasi-contract claims should not be dismissed for the multiple reasons discussed above, they are nevertheless barred by the gist of the action and economic loss doctrines.

The tort and quasi-contract claims are barred under Pennsylvania's “gist of the action” doctrine, which forecloses claims that replicate claims for breach of contract. The “gist of the action” doctrine bars claims that are based or dependent on allegations of nonperformance under

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(W.D.Pa.,2016).

a contract. *Bruno v. Erie Ins. Co.*, 106 A.3d 48, 68-69 (Pa.2014); *Melhorn Sales, Serv. & Trucking Co. v. Rieskamp Equip. Co.*, 2010 U.S. Dist. LEXIS 25398, \*4 (E.D.Pa.,2010).

The Pennsylvania Supreme Court set forth a test for determining the “gist of an action” in *Bruno*, 106 A.3d at 68. Under *Bruno*, if the nature of the claim does not transcend the transactions between the parties and invoke a “broader social duty,” the “gist” of the claim will not sound in tort. All of the claims alleged in the Complaint stem from the 1998 Hygrosol License Agreement that Takeda attaches as Exhibit A to its Complaint.

Takeda has alleged no facts supporting a “broader social duty” giving rise to tort liability. Rather, the Complaint alleges that Mutual suffered economic loss because it paid Hygrosol royalties under the 1998 Hygrosol License Agreement. Such claims do not involve a “broader social duty” that transcends the contract. Nor does Takeda allege anything more than economic loss resulting from disappointed expectations arising from the transaction itself. *Melhorn*, 2010 U.S. Dist. LEXIS 25398, at \*4. *See also Caudill Seed & Warehouse Co. v. Prophet 21, Inc.*, 123 F. Supp. 2d 826, 833-34 (E.D.Pa.,2000) (granting motion to dismiss under “gist of the action” doctrine for alleged misrepresentations that computer software would perform and assist plaintiff’s wholesale business); *Hospicomm, Inc. v. Fleet Bank, N.A.*, 338 F. Supp. 2d 578, 583 (E.D.Pa.,2004)(granting motion to dismiss tort claims because “gist of action” precluded tort claims of agent of customer against bank); *Bruno v. Bozzuto’s, Inc.* 850 F. Supp. 2d 462, 468-69 (M.D.Pa.,2012)(dismissing claims for negligent and fraudulent misrepresentation under the gist of the action doctrine because those claims arose from contractual duties).

Under Pennsylvania law, the economic loss rule bars recovery in tort if a damaged or defective product causes purely economic loss and no personal injuries. *See, e.g., Martin v. Ford Motor Co.*, 765 F. Supp. 2d 673, 684 (E.D. Pa. 2011) (“[T]he doctrine prevents a plaintiff from

recovering economic losses in tort without physical injury”). Under Third Circuit law, the “economic loss” rule applies to quasi-contract claims in exactly the same fashion as it applies to fraud and misrepresentation claims. *Werwinski v. Ford Motor Co.*, 286 F. 3d 661, 681 (3d Cir. 2002).

Each of Takeda’s claims alleges economic injury, and only economic injury, specifically, the royalty payments by Mutual to Hygrosol. Those claims are, therefore, barred by the economic loss rule. *See, e.g., Martin*, 765 F. Supp. 2d at 684 (dismissing statutory fraud (UTCPL), common law fraud, and negligent representation claims with prejudice because the economic loss doctrine barred the claims); *Vaughan v. State Farm Fire and Casualty Co.*, 2014 WL 6865896, at \*4 (E.D. Pa. Dec. 3, 2014) (dismissing UTCPL claim under the economic loss rule) (citing *Werwinski v. Ford Motor Co.*, 286 F. 3d 661, 681 (3d Cir. 2002)).<sup>35</sup>

#### IV. CONCLUSION

For all the forgoing reasons, Takeda’s Complaint must be dismissed. It is barred by *res judicata* because the same claims for the same damages by the same party in interest were dismissed by the state court.

It is also implausible. Even if the drug industry were not so highly regulated by the FDA, and under such scrutiny, Mutual necessarily knew how it manufactured its own generic drugs in its own facility by its own scientists. It is not plausible that it did not know whether or not it

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<sup>35</sup> Although some courts have not permitted the dismissal of intentional misrepresentation claims under the economic loss rule, the Third Circuit reversed that approach in circumstances applicable to this case. The Third Circuit held that the economic loss rule precludes recovery for economic losses resulting from intentional torts if the claims are based on alleged misrepresentations concerning the nature or quality of goods sold. *See Werwinski v. Ford Motor Co.*, 286 F.3d 661, 677, 680-81 (3d Cir. 2002) (the economic loss rule precludes tort claims for “purely economic loss even where plaintiff alleges an intentional tort such as fraud, if the misrepresentation relates to the quality of the good sold”). The allegations of loss pled in the Complaint all relate to a claim that Mutual unknowingly did not use Hygrosol Technology when it manufactured its goods.

used Hygrosol technology. Its conspicuous failure to plead that it did **not** use Hygrosol technology is fatal to its artful *innuendo* and suggestion that Dr. Spireas duped it into thinking it had in 2000 – seventeen (17) years ago. Similarly, its conspicuous failure to name its own co-litigant and “sister company” from the state court action, URL, is fatal and requires dismissal. Takeda did not name the contracting party, URL, as a litigant party, because it would have destroyed diversity.

Its tort claims, which are based on statements made seventeen (17) years ago, thirteen (13) years after Mutual fired Dr. Spireas, and six (6) years after it sued him, are barred by the statute of limitations and by the gist of the action doctrine.

This new federal action filed by Takeda is not a real case. It is a litigation ploy filed in bad faith to exert leverage in other, already pending lawsuits. It must be immediately dismissed in its entirety. Takeda can re-file any real claims before the same state court that is currently presiding over them.

ELLIOTT GREENLEAF, P.C.

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Respectfully, submitted,

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on this day the forgoing was served on all counsel of record pursuant to the Court's ECF service provisions.

Timothy T. Myers

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Date: April 3, 2017